Supplementary file 1:
SOLID TOC Terms of Reference

SOLID Trial Oversight Committee (TOC) Terms Of Reference

I. Background

The SOLID pilot feasibility trial (Supporting Looked After Children and Care Leavers In Decreasing Drugs, and alcohol) is a two year study funded through the NIHR Public Health Research stream. The study aims to assess the pilot feasibility and acceptability of a definitive three-arm multi-centre randomised controlled trial (two behaviour change interventions and care as usual) to reduce risky substance use (illicit drugs and alcohol), and improve mental health in Looked After Children and Care Leavers (LAC aged 12 -20 years). The study will take place in multiple sites in the North East of England and will have two linked phases: 1. Formative study phase, followed by 2. Pilot feasibility randomised controlled trial (RCT).

The Trial Oversight Committee (TOC) (also referred to as the Trial Steering Committee within NIHR correspondence) will comprise of independent experts in child public health, health services research, and trial methodology along with representatives from the internal Trial Management Group (TMG). The Trial Oversight Committee will provide a forum for information exchange, oversight of both the formative research phase and the feasibility trial and provide advisory input. Recommendations made by the TOC will guide the Trial Management Group to deliver the project.

II. The Trial Management Group

Aims and objectives: The Trial Management Group (TMG) group is responsible for ensuring appropriate, effective and timely implementation of the SOLID research study.

The TMG will strive to achieve this aim by fulfilling the following objectives:

- To determine tasks, schedules and deliverables of the SOLID trial.
- To participate in the development and compilation of relevant research and intervention manuals.
- To determine the fidelity of trial interventions.
- To produce a working protocol for the trial and ensure adherence to the protocol.
- To develop a publication protocol.
- To facilitate and support data analysis.
- To determine tasks, schedules and deliverables for report writing and publication of findings.
- To ensure that adequate supervision/support occurs for research staff.

Membership:

Trial Management Group (TMG) consists of the Chief Investigator, Dr Raghu Lingam, the study coordinator, Dr Hayley Alderson, along with all co-applicants of the study and researchers involved with the running of the study.

Dr Rebecca Brown, Dr Ruth McGovern, Professor Eileen Kaner, Ms Denise Howel, Professor Elaine McColl, Professor Janet Shucksmith, Mr Tony Fouweather, Dr Frauke Becker, Dr Heather Brown, Professor Luke Vale, Professor Alex Copello, Dr Paul McArdle, Dr Alison Steele and Ms Louise Carr.

Appendix 1 lists the TMG members and contact details.

III. Trial Oversight Committee

The TOC will provide oversight and expert advice to the TMG on the key study objectives:

Phase 1 Formative Study: To adapt two behaviour change interventions for Looked After Children (LAC) and care leavers to help reduce risky substance use: i, Motivational Enhancement Therapy (MET); ii. Social Behavioural Network Therapy (SBNT). This will be carried out with LAC and care leavers, their carers, drug and alcohol workers, and LAC social workers to ensure acceptability and feasibility of the intervention packages.

Phase 2 Pilot Feasibility RCT: To conduct a three arm pilot RCT (comparing: i. MET, ii. SBNT, and iii. Control – usual care), to determine if rates of eligibility, recruitment and retention of LAC, and acceptability of the interventions are sufficient to recommend a definitive multi-centre randomised controlled trial.

In particular, it will:

1. monitor progress of the SOLID project towards its interim and final objectives.
2. discuss key finding from both the formative research phase and feasibility trial.
3. advise the TMG about how to take the findings of the SOLID feasibility trial to a definitive trial.
4. consider how the results of the project will be disseminated locally, nationally and if appropriate internationally.
5. report back to the NIHR PHR board via the Chair.

Membership

Independent members of the TOC consist of:

Professor Monica Lakhanpaul (Chair), Professor Doug Simpkiss, Profess Jill Francis and Dr Leah Li. Contact details are provided in appendix 1.

Meetings and Reporting

The study coordinator and CI will be responsible for facilitating and organizing meetings for the advisory board in liaison with the chair of the TOC. The TOC will join members of the TMG to discuss key findings from the study and to allow the TMG to feedback progress. The TOC will then be given an opportunity to meet independently of the TMG. They will then be asked to feedback their recommendations.

The TOC will meet annually at a time that is appropriate for reviewing the project implementation progress. Currently two meetings have been scheduled: 1. at end of the

formative research phase and 2. near the end of the feasibility trial. The TOC may also be convened on an ad-hoc basis by the Chair or on the recommendation of the Principal Investigator to consider specific issues.

The Chief Investigator will make use of electronic communications and videoconferencing to facilitate information sharing among Advisory Group members between formal meetings.

The Advisory Group will issue, in a timely manner, a summary record of each of its meetings. Such reports shall be disseminated to members of the TMG via the SOLID admin team and coordinator.

A copy of TOC report shall be shared with the NIHR PHR board as part of study reporting. As per NIHR guidance, the formal point of contact between the TOC and the Public Health Research programme is the Chair of the TOC. If members of the board have any matters that they would wish to bring to the attention of the PHR board, they should inform the TOC Chair, who will then communicate with NIHR.

Term of Office

TOC members will serve for the duration of the current study till March 2018.

Remuneration

Advisory Group members will not receive remuneration for their service. They will however receive all travel expenses and additional expenses in order to attend Advisory Group meetings.

Contact details of members of TMG and TOC

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Trial Oversight Committee (TOC).	Chair of TOC : **Professor Monika Lakhanpaul** Professor of Integrated Community Child Health Population, Policy and Practice Institute of Child Health 30 Guilford Street London WC1N 1EH m.lakhanpaul@ucl.ac.uk **Dr Doug Simpkiss** University of Warwick Coventry CV4 7AL D.E.Simkiss@warwick.ac.uk **Prof Jill Francis** Professor of Health Services Research Health Services Research & Management City University of London Jill.Francis.1@city.ac.uk **Dr Leah Li** Senior Lecturer ICH Pop, Policy & Practice Prog UCL GOS Institute of Child Health Faculty of Pop Health Sciences leah.li@ucl.ac.uk